UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,425	02/12/2004	Paul R. Sanberg	1372.129.PRC	4329

21901 7590 06/27/2007

SMITH HOPEN, PA
180 PINE AVENUE NORTH
OLDSMAR, FL 34677

EXAMINER	
KIM, TAEYOON	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,425	SANBERG ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/12/04 and 5/24/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/10/04, 6/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-18), and a species election of "myocardial infarction" in the reply filed on April 10, 2007 is acknowledged.

Claims 19-26 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-18 have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 18 disclose the term "milliliter." It is not clear what would be the objective of the term. It could be any solution, which is not disclosed in the claim.

Claim 13 recites the limitation "the scar" in 2nd line. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10 and 12-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Dengler et al. (Herz, 2002).

Claims 1-4, 6-10 and 12-16 are drawn to a method of treating myocardial infarction comprising administering an effective amount of a composition comprising a human umbilical cord blood cell to a human patient in need thereof, wherein the umbilical cord blood cell differentiates into a cardiac muscle (claims 1-4 and 12-13); a limitation to the human umbilical cord blood cell being a mesenchymal cell (claims 8 and 16); a limitation to the umbilical cord blood cell being administered directly to heart tissue (claims 9 and 14) or systemically (claims 10 and 15).

Dengler et al. teach a method of treating myocardial infarction by administering umbilical cord stem blood cells directly into the heart tissue or systemically (intravenously) to a human patient in need thereof (see entire document; especially p. 604, right column and Fig. 1 in p.601).

Claims 2 and 13 contain a "wherein" clause that merely states the result of the limitations in the claim and therefore, adds nothing to the patentability or substance of the claim. Therefore, this phrase does not limit the claim. See *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 USPQ2d 1747 (Fed. Cir. 2001).

Nevertheless, Dengler et al. teach the method of administering umbilical cord blood stem cells would regenerate cardiac tissue (muscle tissue) upon the treatment

tissue upon the treatment (see p.604, right column), and also teach the result of preventing further scar tissue formation and minimizing regional scarring (see p.599, left column, 2nd paragraph and p.601, left column).

Thus, the reference anticipates the claimed subject matter.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (2001; IDS ref.) in light of Lim (1999).

Claims 1 and 11 are drawn to a method of administering a composition comprising umbilical cord blood cells to an individual with a circulatory disorder (claim 1) and a limitation to the umbilical cord blood composition comprising at least about 6 million white blood cells per milliliter of the composition (claim 11).

Chen et al. teach a method of administering umbilical cord blood into rats after stroke.

Although Chen et al. do not teach that the blood contains white blood cells at least about 6 million cells per milliliter of the composition, it would be considered as an inherent property of umbilical cord blood to contain white blood cells because Lim et al. teach the number of white blood cells in umbilical cord blood being more than 11 million per milliliter of umbilical cord blood (see Table 1).

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 11, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dengler et al. (supra) in view of Broxmeyer (1995; IDS ref) and in further view of Lim et al. (supra), Anversa (US 2002/0061587) and Edelberg et al (US 2003/0091547).

Claims 5, 11, 17 and 18 are drawn to a limitation to the umbilical cord blood cells being administered within approximately 48 hours after the onset of myocardial infarction (claims 5 and 17); a limitation to the umbilical cord blood composition comprising at least about 6 million white blood cells per milliliter of the composition (claims 11 and 18).

Dengler et al. anticipate the limitation of claims 1 and 12, and therefore render obvious (see above).

Dengler et al. do not teach the presence of at least 6 million white blood cells in the composition comprising umbilical cord blood cells.

Broxmeyer et al. teach the use of umbilical cord blood.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the umbilical cord blood stem cells of Dengler et al. with the umbilical cord blood, which comprises stem cells/progenitor cells as well as white blood cells according to Lim et al.

The skilled artisan would have been motivated to make such a modification because Dengler et al. disclose various different cells for treatment of myocardial infarction including endothelial progenitor cells (see Table 1), and Edelberg et al. teach the use of endothelial progenitor cells isolated from umbilical cord blood in treatment of myocardial infarction (see paragraph [0018]). Furthermore, Broxmeyer teaches that umbilical cord blood contains hematopoietic stem and progenitor cells (see whole document), and hematopoietic stem cells can be used in treatment of myocardial infarction taught by Anversa (see paragraph [0005]). Since hematopoietic stem cells and endothelial progenitor cells are used for treatment of myocardial infarction, and it is inherent property of umbilical cord blood contain hematopoietic stem cells and endothelial progenitor cells, a person of ordinary skill in the art would have a motivation to use umbilical cord blood in place of isolated umbilical cord blood stem cells of Dengler et al., and reasonably expect success in using umbilical cord blood.

Although Dengler et al. do not teach the time frame of administration of the cell composition or the presence of at least about 6 million white blood cells in the composition, it would have been obvious for a person of ordinary skill in the art to routinely optimize because the time point when the composition being administered

used in the claimed method is a result-effective variable. As such, the variables would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed atl a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); ** In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the :references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Accordingly, the

claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Patent Examiner
Art Unit 1651

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651